MAY 1 1 2010

K100211/S002

510(k) SUMMARY

1.0 Submitter

Name	**Shen Wei (USA) Inc.**
Street Address	33278 Central Ave., Suite 102 Union City, CA. 94587
Phone No.	(510)429-8692
Fax No.	(510)487-5347

Date of Summary Prepared: 1/20/2010

2.0 Contact Person:

Name:	Mr. Albert T Li
Phone No.	(510)429-8692
Fax No.	(510)487-5347

3.0 Device Identification:

Glove Proprietary or Trade Name: (Multiple Names) Pearlescent Black Textured Powder- Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with Protein Content Labeling Claim (50 micrograms or less)
Common Name: Exam gloves
Classification Name: Patient examination glove (per 21 CFR 880.6250)
Classification Information: Class I Latex patient examination glove 80LYY, powder-free and meeting all the requirements of ASTM D 3578-05e1 Standard Specification for Latex Examination Gloves for Medical Application.

4.0 Identification of the Legally Marketed Device:

Class I latex patient examination gloves 80LYY, powder free and meeting all the requirements of ASTM D 3578-05e1 Standard Specifications for Latex Examination Gloves for Medical Application.

5.0 Description of the Device:

The Pearlescent Black Textured Powder- Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with (Protein Content Labeling Claim) Contains 50 micrograms or less of Total Water Extractable Protein per gram which had been submitted and cleared under 510(k) number K013793

The difference in this submission is:

a) Change of color to be Pearlescent Black. (MSDS Attachment C)

Reference Documents:

a) SOP for Random Sampling of pH 5.0-5.5 Gloves to Ensure pH 5.0-5.5 Coating of Gloves (Attachment A)
b) Testing to Confirm pH 5.0-5.5 of gloves (Attachment B)
c) Characterization and Application of Aloe Vera at pH 5.0-5.5 (Attachment Four)

The modification of the device does not affect the intended use of the device as well it does not affect its safety and effectiveness. The indication for use and proposed labeling for the device are illustrated in subsequent sections

The Pearlescent Black Textured Powder- Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with Protein Content Labeling Claim meets all the requirements of ASTM D 3578-05e1 Standard Specification for Latex Examination Gloves for Medical Application.

6.0 Intended Use of Device:

A disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. The device is single use only.

7.0 Summary of Technological Characteristics for Modified Device:

The Pearlescent Black Textured Powder- Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with Protein Content Labeling Claim are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	**Standards**	**Device Performance**
Dimensions	ASTM D 3578-05e1	Meets
Physical Properties	ASTM D 3578-05e1	Meets
Freedom from pinholes	ASTM D 5151-99	Meets (AQL 2.5)
Powder Residual	ASTM D 6124-06	Meets (<2mg/glove)
Protein Level	ASTM D 5712-05	Meets (<50 ug/g)
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
Biocompatibility	Dermal Sensitization	Passes (Not a primary skin irritant)

8.0 Conclusion:

The Pearlescent Black Textured Powder- Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with Protein Content Labeling Claim will perform according to the glove performance standards reference in section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Albert Li
Project Manager
Shen Wei (USA), Incorporated
33278 Central Avenue, Suite 102
Union City, California 94587

MAY 11 2010

Re: K100211
Trade/Device Name: Pearlescent Black Textured Powder-Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with Protein Content Labeling Claim (50 micrograms or less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 26, 2010
Received: April 28, 2010

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 100211/5002

Attachment Two

INDICATION FOR USE

Applicant: Shen Wei (USA) Inc.

Device Name: Pearlescent Black Textured Powder- Free Latex Examination Gloves, Coated with Aloe Vera at pH 5.0-5.5, with Protein Content Labeling Claim (50 micrograms or less)

Indication For Use:

A disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ **Or** **Over-The Counter** ___X___
Per 21CFR 801.109 (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100211